JUL 2 4 2000

Otto Bock
ORTHOPEDIC INDUSTRY, INC.

K001890
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510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	Otto Bock Orthopedic Industry, Inc.
2.	*Address:*	3000 Xenium Lane North Minneapolis, MN 55441
3.	*Telephone:*	612-553-9464
4.	*Contact Person:*	E.P. (Bert) Harman
5.	*Date Prepared:*	June 16, 2000
6.	*Registration Number:*	2182293

B. Device

1.	*Name:*	Sherpa/Kodiak Cub Mobility System (Manual Wheelchair)
2.	*Trade Name:*	Sherpa/Kodiak Cub Mobility System (Manual Wheelchair)
3.	*Common Name:*	Manual Wheelchair
4.	*Classification Name:*	Manual Wheelchair
5.	*Product Code:*	IOR
6.	*Class:*	I
7.	*Regulation Number:*	890.3850

Otto Bock Orthopedic Industry, Inc.
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C. Identification of Legally Marketed Devices

1. *Name:* Zippie TS
2. *K Number:* K890050
3. *Date Cleared:* February 8, 1989

D. Description of the Device

The Sherpa/Kodiak Cub wheelchair is a pediatric tilt-in-space mobility base that will accommodate a seating system in order to form a complete seating and positioning mobility device for the user. The chair can be configured to be propelled by its user or an attendant. It is intended to be used for children with special needs such as cerebral palsy, traumatic brain injury, etc. It will also be capable of being transported in a motor vehicle if necessary.

The Sherpa/Kodiak Cub will offer its user 90°-130° of recline, 55° of tilt, seat depth adjustment, seat width adjustment, 3 inches of seat drop, anti-tip tubes, wheel locks, various sizes of front and rear wheels, and height adjustable push handles.

The Sherpa/Kodiak Cub is propelled by its user or an attendant and will be set up to the specific measurements of its user. The seating system that connects to the frame will do so in two ways, either with drop hook hardware or a quick release interface. If the seating system that connects with a quick release interface is used, it may also be removed and placed on the Panda home underframe if necessary.

The Sherpa/Kodiak Cub is similar to the Zippie TS pediatric tilt-in-space mobility base manufactured by Sunrise Medical. Combined with a modular seating and positioning system, it forms a complete pediatric mobility device. It offers tilt angle adjustability and back angle adjustability, and can be transported by motor vehicle if necessary.

E. Intended Use Statement

The Sherpa/Kodiak Cub is an aluminum/steel tilt-in-space mobility system manual wheelchair for everyday use. This wheelchair provides mobility to physically challenged persons. The wheelchair can also be pushed by an assistant grasping the handles attached to the back rest. The wheelchair can also be moved by the user propelling the handrims, which are attached to the rear (drive) wheels.

F. Technological Characteristics Summary

The Sherpa/Kodiak Cub Wheelchair is substantially equivalent to the Zippie TS, cleared on February 8, 1989 as K890050.

Each wheelchair is a tilt-in-space mobility system manual wheelchair for everyday use, with push or manual design, adjustable back angle, flip-up armrests, adjustable seat heights, and similar seat widths, depths, weights and wheels.

The Sherpa/Kodiak Cub was tested by TÜV Product Service to the following standards:

- prEN 12182
- prEN 12183
- EN/ISO 10993
- EN/ISO 9999
- ISO 7176-1
- ISO 7176-8
- ISO 7176-11
- ISO 7176-3
- ISO 7176-16
- ISO 7176-15
- EN 1041

with the conclusion that "the presented unit was found to meet the requirements of the test specification."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 4 2000

Mr. E.P. Bert Harman
CEO/President
Otto Bock Orthopedic Industry, Inc.
3000 Xenium Lane North
Minneapolis, Minnesota 55441

Re: K001890
Trade Name: Sherpa/Kodiak Cub Mobility System
Regulatory Class: I
Product Code: IOR
Dated: June 16, 2000
Received: June 21, 2000

Dear Mr. Harman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: ~~*To be determined*~~ K001890

Device Name: Sherpa/Kodiak Cub Mobility System (Manual Wheelchair)

Indications for Use:

- Manual transportation device for person who are unable to walk or have a walking impediment, propulsion by the user or an attendant.

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001890

Prescription Use _____ OR OVER-THE-COUNTER USE ✓
(optional Form 1-2-96)